Infosys E2B R3 Validation Utility

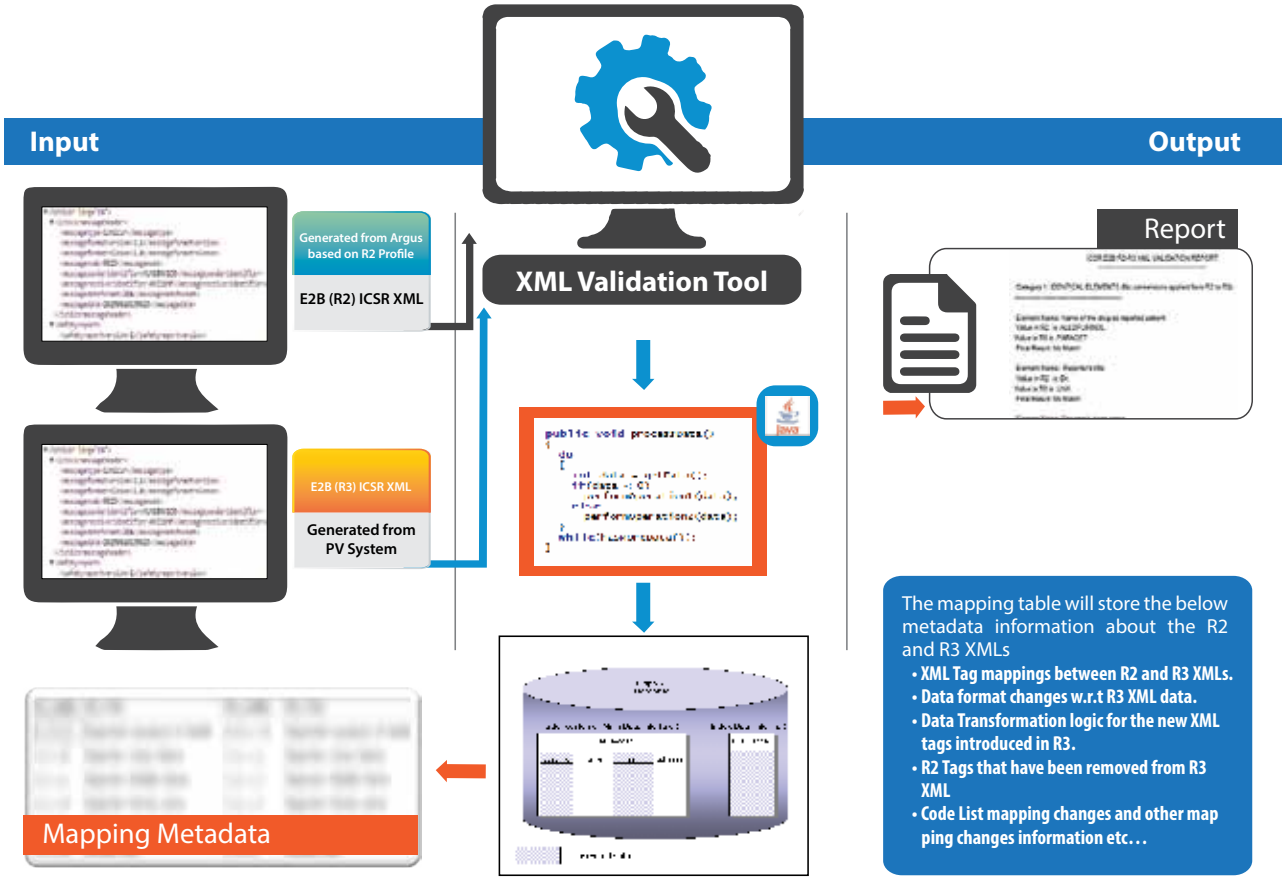
Today, the E2B standard for submission of adverse events is an essential component of global pharmacovigilance and drug safety systems. The E2B standard has undergone multiple revisions since its adoption in 2001. The E2B (R3) guidelines encompass advances in the pharmacovigilance sciences made over the last few years and requires capturing rigorous data with increased frequency and granularity. Therefore, this standard will enable life sciences companies to improve the consistency and accuracy of adverse event reporting. All life sciences companies must be E2B (R3) compliant by the end of 2016, failing which they will attract significant legal implications.

They will have to enable their processes and PV systems to maintain the coexistence of R2 and R3 versions during the transition period and must manage these challenges effectively:

- Organizations must report substantial amount of information from the drug safety applications, requiring significant time and effort from pharmacovigilance and regulatory departments for implementing the key changes in their PV processes and systems
- Coexistence of both the E2B formats (R2 and R3) are needed based on the reporting region and their timelines for the R3 compliance. In addition, organizations need the support of safety applications such as Oracle Argus, which have not yet moved to the R3 standard
- Rigorous testing is necessary to make E2B (R3) Report Generation Tool defect free - as they will be transitioned to the R3 version

Infosys E2B R3 Extensible Markup Language (XML) Validation Utility

This utility helps life sciences companies accelerate E2B transition from R2 to R3 with a powerful testing tool that takes care of both the structural and granular level validation of R3 with respect to the existing reporting standards. It systematically accelerates testing cycles during the implementation of E2B (R3) compliant drug safety applications and generates E2B R3 XML. The solution framework is flexible enough to adapt to any level of customizations and no additional setup is required at the test site for the implementation.



Salient features:

- Validates the R3 XML for structure against the standard ICH R3 structure template
- Carries out a detailed tag-by-tag validation both for data integrity and R3 compliance
- Covers all aspects of R3 changes in scope - starting from date format changes to complex structural changes
- Validation report categorizes the discrepancies into different buckets for ease of tracking and error identification
- Scalable and extensible to process large amounts of data

Solution benefits

- Accelerates the testing process and reduces the test cycle duration by at least 25 - 30 percent
- Allows automated testing of the complete XML and avoids manual tag-by-tag validation
- Offers extensive defect capturing abilities coupled with simplified yet detailed report
- Flexible design to adapt to changes in regulatory guidelines
- Portable solution that can run from any laptop or desktop

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